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CANNON BUILDING
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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, June 18, 2014 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	August 20, 2014

MEMBERS PRESENT

Kimberly Robbins, R.Ph, Professional Member, Vice President
Sandra Zaragoza, R.Ph, Professional Member
Susan Esposito, R.Ph, Professional Member
Tejal Patel, R.Ph, PharmD, Professional Member
Bonnie Wallner, R.Ph, Professional Member
Jay Galloway, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

Joli Martini, R.Ph., PharmD, Professional Member, President
Kenneth Sellers, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Mangler, Director, Division of Professional Regulation
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Samantha Nettesheim, Pharmacist Administrator
Michelle McCreary, Pharmacy Compliance Officer

ALSO PRESENT

Mary Ann Christ
Don Holst
Ryan Greenly
Melanie Standridge
Tien N Nguyen
Monica Ngo
Suzanne Raab-Long
Kristine Genba
Jennifer Reyes
Nancy Sawyer

Allegra Spiezio
Jaime Frink
Umsa Uppal
Pooja Gupta
Him Shah
Marlene Scodden
Janis Levit
Sandra Robinson
Abhi Shek De
Bill Harbester
Chirag Patel
Kevin Musto

CALL TO ORDER

Ms. Robbins called the meeting to order at 9:31 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Esposito, seconded by Ms. Patel, to approve the meeting minutes as amended for April 16, 2014. The motion unanimously carried.

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito, to approve the meeting minutes for April 29, 2014. The motion unanimously carried.

PRESIDENT'S REPORT

Ms. Robbins read a written statement provided by Ms. Martini due to her planned absence which shared the following:

Since the last Board of Pharmacy meeting I attended the NABP meeting in Phoenix, AZ with Tejal Patel and Dave Dryden. This was my first time attending NABP and it was a very enjoyable experience. I had the opportunity to meet several influential people in our profession and learned a lot about how other Boards of Pharmacy accomplish goals. I worked with several members of the Board over the last month to oppose the passing of SB118. I would like to take a minute to thank Julie Miro Wenger for all of her help and dedication to the Board for what she did over the last several months with regard to this process. Unfortunately, the Governor did sign the bill into law on May 28th despite our efforts. Respectfully submitted, Joli Martini, PharmD.

Ms. Robbins also recognized David Dryden receiving the NABP, John F Adkinson Service Award at the annual meeting in May.

UNFINISHED BUSINESS

Complaint Status

13-03-11 – Assigned to Hearing Officer
13-09-11 – Assigned to Hearing Officer
13-12-11 – Forwarded to Office of Attorney General
13-19-11 – Forwarded to Office of Attorney General
13-09-12 – Assigned
13-01-13 – Forwarded to Office of Attorney General
13-02-13 – Assigned
13-03-13 – Assigned
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Assigned
13-06-13 – Forwarded to Office of Attorney General
13-07-13 – Assigned
13-08-13 – Assigned
13-09-13 – Assigned
13-11-13 – Forwarded to Office of Attorney General

13-13-13 – Forwarded to Office of Attorney General
13-14-13 – Assigned
13-15-13 – Assigned
13-16-13 – Assigned
13-17-13 – Assigned
13-18-13 – Assigned
13-19-13 – Assigned
13-20-13 – Assigned
13-21-13 – Assigned
13-22-13 – Assigned
13-23-13 – Assigned
13-24-13 – Assigned

Review/Signing of Board Order – Loren A Mays

Ms. Kelly, Deputy Attorney General will prepare and forward the order for Ms. Martini's signature. The order was previously approved by the board.

Review of Applications for Final Denial

None

Re-Review of Tabled Applications

Vet Meds & More, A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to approve the application. The motion unanimously carried.

LCRx, LLC., A motion was made by Mr. Galloway, seconded by Ms. Zaragoza to approve the application. The motion unanimously carried.

SB118 Status Update

Passed legislation and signed into law by Governor Jack Markell on May 28, 2014.

Review of Outsourcing Facility Licensure

Mr. Dryden reported that during the most recent FDA meeting it was determined that Outsourcing Facilities must apply with the FDA for approval based on 503(a) and 503(b). He stated that most states are licensing these facilities as well. Ms. Kelly agreed that Delaware statute supports this licensure type in current form. Mr. Dryden stated that he could work with the division to create such a license type to support licensing of "Outsourcing Facilities" if the board so desires. A motion was made to create a license type of "Pharmacy Outsourcing Facility" to allow these facilities to become licensed in Delaware by Ms. Zaragoza seconded by Ms. Esposito. The motion carried unanimously.

Review of Practitioner/Pharmacy Ownership

Mr. Dryden provided historical information relating to dispensing practitioners dispensing large quantities of controlled substances. This was addressed by recent legislation limiting the quantity prescribed to 72 hours by the Controlled Substance Committee. There have been recent inquiries related to practitioners who may wish to own their own pharmacy. Mr. Dryden provided the board with recommendations for possible amendments to the statute for review related to this issue. Mr. Dryden will also provide statistics related to the number of states that have already added legislation to their statute during the next meeting. This will remain on the agenda for the August meeting.

NEW BUSINESS

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0004560 David L. Snow
A1-0004561 Victor G. Spearman
A1-0004562 Monica Ngo

- A1-0004563 Kelly A. Klakowicz
- A1-0004564 Karen Beth Main
- A1-0004565 Hugh A. Smith
- A1-0004566 Lisa A. Odenwelder
- A1-0004567 Martin F. Blood
- A1-0004568 John Mathew
- A1-0004569 Linus Louis
- A1-0004570 Mitul T. Vora
- A1-0004571 Staci J. Welch
- A1-0004572 Antonina Nikolaidis
- A1-0004573 Valerie Fay Rentfro
- A1-0004574 Ann Marie Gill
- A1-0004575 Paul J. Burrichter
- A1-0004576 Adam J. Talbot
- A1-0004577 Messiah K. Moore
- A1-0004578 Conroy S. Whitely
- A1-0004579 Utkarsh B. Doshi
- A1-0004580 Allison R. Turner
- A1-0004581 Daniel R. Rogers
- A1-0004582 Tri Minh Nguyen
- A1-0004583 Gounathan Adly
- A1-0004584 Kristine A. Ziemba
- A1-0004585 Padraic E. Keen

A motion was made by Ms. Zaragoza, seconded by Ms. Wallner to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

- A7-0002362 Marissa Kathleen Yarnall
- A7-0002363 Mayur I. Patel
- A7-0002364 Jeenha Park
- A7-0002365 Zein elabdeen Elbagir Eissa
- A7-0002366 Krish A. Patel
- A7-0002367 Kenneth H. Harrington
- A7-0002368 Juliette M. Fombi
- A7-0002369 Priyankkumar J. Patel
- A7-0002370 Brittany M. Snyder

A motion was made by Ms. Esposito, seconded by Ms. Wallner to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

- A9-0001420 Destrehan Discount Pharmacy
- A9-0001421 Specialty Medical Drug Store
- A9-0001422 Assured RX LLC
- A9-0001423 Pharmacy Services Inc.
- A9-0001424 TCS Labs LLC
- A9-0001425 Davis Drug, Inc.
- A9-0001426 Biorx, LLC
- A9-0001427 Home Care Services Inc
- A9-0001428 Longevity Drugs LLC dba Tru-Valu Drugs
- A9-0001429 North Coast Medical Supply
- A9-0001430 Vital Rx, Inc. dba/Atlantic Pharmacy and Compounding
- A9-0001431 Leiter's Compounding
- A9-0001432 Santa Cruz Rx
- A9-0001433 The Compounding Facility

A9-0001434 Leehar Distributors Inc.
A9-0001435 PRN Rx, LLC
A9-0001436 HM Compounding
A9-0001437 American Rx, LLC
A9-0001438 Kroger Columbus Central Fill
A9-0001439 Aureus Pharmacy
A9-0001440 Advanced Pharmacy, LLC
A9-0001441 Allcare Plus Pharmacy Inc.
A9-0001442 Village Green Apothecary
A9-0001443 CCN America, LP Coordinated Care Network Pharmacy
A9-0001444 National Compounding Company, Inc.
A9-0001445 Marley Drug
A9-0001446 Lenox Hill Pharmacy Inc
A9-0001447 Rx E-fill Solutions
A9-0001448 Synergy Pharmacy Services, Inc.
A9-0001449 Sonexus Health Pharmacy Service, LLC
A9-0001450 New Life Pharmacy, LLC
A9-0001451 My Favorite Pharmacy, LLC.
A9-0001452 OncoMed Pharmaceutical Services of Jersey City
A9-0001453 Integrated Health Concepts, Inc.
A9-0001454 CPP Pet Care
A9-0001455 The Medicine Shoppe # 1905
A9-0001456 David Pharmacy, LLC
A9-0001457 Llewellyn's, Inc.

A motion was made by Mr. Galloway, seconded by Ms. Zaragoza to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001845 True Science Holdings, LLC
A4-0001872 Bryant Ranch Prepack
A4-0002085 MWI Veterinary Supply Co, DBA Ivesco
A4-0002086 INO Therapeutics LLC
A4-0002087 HealthSource Distributors, LLC
A4-0002088 The Procter & Gamble Distributing LLC
A4-0002089 The Procter & Gamble Distributing LLC
A4-0002090 The Procter & Gamble Distributing LLC
A4-0002091 The Procter & Gamble Distributing LLC
A4-0002092 The Procter & Gamble Distributing LLC
A4-0002093 The Procter & Gamble Distributing LLC
A4-0002094 The Procter & Gamble Distributing LLC
A4-0002095 Exel Inc
A4-0002096 Freedom Pharmaceuticals, Inc.
A4-0002097 Mission Pharmacal Company
A4-0002098 Amatheon, Inc.
A4-0002099 Kenco Bracco
A4-0002100 DSC Logistics, Inc.
A4-0002102 Priority Air Express, LLC
A4-0002103 Abbott Laboratories Inc.
A4-0002104 FFF Enterprises, Inc.

A motion was made by Ms. Esposito, seconded by Mr. Galloway to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000110 Medic-Aire Medical Equipment, Inc.

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0000664 Rite Aid #4916

A3-0000966 Harris Teeter Pharmacy

A3-0000968 Delaware CVS Pharmacy, LLC dba CVS/Pharmacy #10103

A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with:

Maryann Christ, Rockford Center

Kristine Ziemba, Rockford Center

Candice O'Garro, CVS Caremark Store #1911(not in attendance, PIC interview previously completed)

Jaime Frink, CVS Caremark Store #3042(PIC interview previously completed)

Jennifer Reyes, CVS Caremark Store #3038

Monica Ngo, CVS Caremark Store #10103

Pooja Gupta, Rite Aid Bear #11175*

Chirag Patel, Rite Aid Wilmington #1658*

Hiren Shah, Rite Aid Wilmington #1780*

Umsa Uppal, Rite Aid Smyrna #11195*

Consultant Pharmacist Interviews

None

Board Review and Consider of Consent Agreement

Robert Koch, board review not required. Consent Agreement from another state.

Restore Health Pharmacy, LLC. - A motion was made by Mr. Galloway, seconded by Ms. Zaragoza to approve the Consent Agreement. The motion unanimously carried.

Anthony J Franzosa III - A motion was made by Ms. Zaragoza, seconded by Ms. Esposito to deny the Consent Agreement. Ms. Wallner abstained. The motion carried.

Vamsi Krishna Guedy Venkata - A motion was made by Mr. Galloway, seconded by Ms. Wallner to approve the Consent Agreement. The motion unanimously carried.

Review of Applications by DAG

Pharmacy board DAG Eileen Kelly provided guidance on the following disciplinary actions for applications received, followed by the board ruling:

Facility: White Drug #61, a motion was made by Mr. Galloway, seconded by Ms. Zaragoza, to approve the application. The motion unanimously carried.

Facility: Premium Rx National, LLC., a motion was made by Ms. Esposito, seconded by Ms. Zaragoza, to table the application. The motion unanimously carried.

Facility: Caraco Pharmaceutical Laboratories, Ltd. (Wixom, MI), a motion was made by Mr. Galloway, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Caraco Pharmaceutical Laboratories, Ltd. (Detroit, MI), a motion was made by Mr. Galloway, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

Facility: Smith & Nephew, Inc., a motion was made by Ms. Zaragoza, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Pharmacist: Charlotte Lopacki, a motion was made by Ms. Zaragoza, seconded by Ms. Wallner, to approve the application. The motion unanimously carried.

Pharmacist: Amber L Myers, a motion was made by Ms. Zaragoza, seconded by Ms. Esposito, to approve the application. The motion unanimously carried.

CE Approval Requests

David Kudish, a motion was made by Ms. Zaragoza, seconded by Ms. Wallner, to approve the CE request. The motion unanimously carried.

Piken Patel, a motion was made by Ms. Zaragoza, seconded by Ms. Wallner, to approve the CE request. The motion unanimously carried.

Evelyn N King, a motion was made by Ms. Zaragoza, seconded by Ms. Esposito, to approve the CE request, Ms. Wallner abstained. The motion unanimously carried.

Kelly Cantwell-McNellis, a motion was made by Ms. Esposito, seconded by Ms. Zaragoza, to table the CE request for more information. The motion unanimously carried.

Nominations for Board President & Vice President

Continued: until August meeting due to the absence of Joli Martini, a motion was made by Ms. Wallner, seconded by Ms. Zaragoza, to continue nominations until August 20, 2014. The motion unanimously carried

24 Del. C. §2512 Issuance and Renewal of Licensure Review

Mr. Dryden spoke about changes in the statute requiring practitioners and pharmacists to complete Continuing Education related to Controlled Substances related to 24 Del. 2512(c)1,2,3. He expressed that the board will need to formulate rules and regulations to define the requirements. The Board agreed that this requirement will be for the 2016 renewal period. Mr. Dryden and Ms. Kelly will work to create proposed regulations changes to be reviewed at the next scheduled meeting.

Mr. Dryden will also send out an alert providing the current continuing education requirements for the 2014 renewal period. This information will also be included in the newsletter.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel and David Dryden

SB118 was signed into law by Governor Jack Markell on May 28, 2014 despite the board's opposition.

Continuing Education – Joli Martini, Bonnie Wallner, and David Dryden:

Mr. Dryden asked if the upcoming DEA symposium can be approved for CE credits. The board approved to accept CE credits for this event.

Consumer Affairs – Ken Sellers and Jay Galloway:

No Report

Professional Liaisons – Kim Robbins and Sandra Zaragoza:

Ms. Zaragoza reported that there was no quorum during the DPS meeting. No official business was conducted.

Controlled Substance Liaisons – Joli Martini, Jay Galloway and David Dryden:

Mr. Dryden reported that an emergency hearing was held to provide a recommendation for guidelines related to ER Hydrocodone for review and approval by the Secretary of State.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Sandy Robinson, Brenda Pavlic, Sandra Zaragoza, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

Mr. Dryden reported that recommended changes are very close to being completed. He will provide an update during the next scheduled meeting. Mr. Dryden provided information related to "Office Use" regulatory changes needed to mirror FDA requirements. This will be discussed during the next scheduled meeting.

Pharmacy Technician Licensure Committee – Kim Robbins, Tejal Patel, Kevin Musto, Maryanne Holzapfel, Anne Pyle, Sandy Esposito and David Dryden:

Ms. Robbins reported that the committee is very close to closure on the recommended statute changes and the committee will meet after the next scheduled meeting.

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:
Ms. Wenger reported that no meetings have been held due to prior obligations with pressing legislation. Meetings should resume in September.

BOARD CORRESPONDENCE

Email: from Michael C King, R.Ph. (DHSS), the email was distributed to the board, Mr. Dryden will also discuss with Ms. Joli Martini and draft a response based on input from the board.

NABP: “Honors Leaders” handout provided.

NABP: “Delegates Approve Eight Resolutions at the NABP 110th Annual Meeting” handout provided.

NABP: “New Educational Video for Pharmacists Address Prescription Drug Abuse” handout provided.

iHealthBeat: “Lawmakers, Courts Limit Police Access to State Rx Drug Databases” handout provided.

Walgreens: Letter from Mr. Daniel Luce was presented for review.

EXECUTIVE SECRETARY AND INSPECTION REPORT - David Dryden, Samantha Nettesheim, Michelle McCreary

Mr. Dryden attended the annual NABP meeting. It was a very productive meeting. Mr. Dryden spoke at the annual DPS meeting. Mr. Dryden and Ms. McCreary have been completing inspections and training is continuing. Mr. Dryden is also on the Executive Board for NASCA and has been involved in several conference calls and meetings. Ms. Nettesheim stated that NJ is online with the PMP and they are very close to utilizing the data. Ms. McCreary stated through her inspections she is finding that the new patient counseling legislation is not being properly administered. She stated that at least one pharmacy is utilizing an alert tagging system to alert the cashier or technician that a patient counseling session should occur. This has been helpful in ensuring that patient counseling occurs as required.

NEWSLETTER UPDATES

None

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

Mr. Kevin Musto reported that volunteer pharmacists are needed for KI (potassium iodine) distribution in Middletown on July 31st at the Middletown Fire Station and August 28th at the Appoquinimink State Service Center.

Mr. Don Holst asked if you can be a Delaware licensed pharmacist and access New Jersey PMP data. Ms. Nettesheim stated that Delaware licensed Pharmacists do have access to New Jersey data.

NEXT SCHEDULED MEETING

The next meeting is scheduled for August 20, 2014 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the board. A motion to adjourn was made by Ms. Esposito, seconded by Ms. Zaragoza. The motion unanimously carried at 11:55 am.

Respectfully submitted,



Christine Mast
Administrative Specialist III